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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,795	04/24/2001	Jonathon J. Lipman	70788	6804

22242 7590 11/24/2003

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EXAMINER	
MCCROSKY, DAVID J	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,795	LIPMAN, JONATHON J.	
	Examiner	Art Unit	
	David J. McCrosky	3736	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,5,9,11,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9,11,18 and 19* is/are allowed.

6)☒ Claim(s) *4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: "if benefit is claimed under 35 U.S.C. 120, 121 or 365(c) the specific reference required ... must include the relationship (i.e., continuation, divisional or continuation-in-part) between the applications ...." MPEP 201.11. The relationship of the present application to the PCT application (continuation or continuation-in-part) is not stated. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bui et al in view of Wilson et al and Togawa. Bui et al teach a method of monitoring pain for automatically controlling the level of medication. Questions pertaining to the level of pain are answered on a scale from 0 to 10. A processor processes the answers and alters the rate and/or dose accordingly. See col. 11, l. 39 to col. 12, l. 59 and col. 13, ll. 44-57. Bui et al further teach a red LED for indicating an alarm, which would gain the attention of medical personnel or signal that patient attention is required. Bui et al do not teach delivering a pain questionnaire at each of a series of time points. However, Wilson et al teach a method of monitoring pain with an infusion apparatus and patient communication means. The infusion apparatus has a display, which delivers questions to the patient. The recorded answers are stored in a non-volatile memory and analyzed

by a physician to determine effectiveness of a particular infusion therapy. See col. 15, ll. 29-36. The questions are asked before and after the infusion (series of time points) to determine the effects of the infusion as noted by the patient. The questions pertain to the level of pain experienced, which is rated on a scale of 1 to 5. Wilson et al further teach asking questions according to characteristics relating to the patient, the medicant to be infused, or the programmed infusion mode. See col. 16. Bui et al and Wilson et al do not teach the particulars of the alarm. However, Togawa teaches that automatic alarm functions in patient monitors are well known in the art. When a single value is expressed (such as the above pain rating scale) an alarm condition is determined by setting a level or range. See last paragraph. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Bui et al, with delivering a pain questionnaire at a series of time points, as taught by Wilson et al, and the alarm of Togawa, to determine the effects of the infusion as noted by the patient and provide an automatic means for notifying a caregiver.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bui et al in view of Wilson et al. Bui et al teach a method of monitoring pain for automatically controlling the level of medication. Questions pertaining to the level of pain are answered on a scale from 0 to 10. A processor processes the answers and alters the rate and/or dose accordingly. See col. 11, l. 39 to col. 12, l. 59 and col. 13, ll. 44-57. Bui et al do not teach delivering a pain questionnaire at each of a series of time points. Wilson et al teach a method of monitoring pain with an infusion apparatus and patient communication means. The infusion apparatus has a display, which delivers questions

to the patient. The recorded answers are stored in a non-volatile memory and analyzed by a physician to determine effectiveness of a particular infusion therapy. See col. 15, ll. 29-36. The questions are asked before and after the infusion (series of time points) to determine the effects of the infusion as noted by the patient. The questions pertain to the level of pain experienced, which is rated on a scale of 1 to 5. Wilson et al further teach asking questions according to characteristics relating to the patient, the medicant to be infused, or the programmed infusion mode. See col. 16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Bui et al, with delivering a pain questionnaire at a series of time points, as taught by Wilson et al, to determine the effects of the infusion as noted by the patient.

Response to Arguments

Applicant's arguments with respect to claims 4 and 5 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 9, 11, 18 and 19 are allowed. See previous office action for reasons for allowance.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Johnson discloses many types of questionnaires and computer processing the answers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. McCrosky whose telephone number is 703-305-1331. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

DJM

ERIC F. WINAKUR
PRIMARY EXAMINER